

**REMARKS**

Favorable reconsideration of the subject application as amended above is respectfully requested in view of the comments below.

Claims 51-62, 73-75 and 154 are pending in the subject application. Claim 51 has been amended to recite the five specific hybridoma from which the claimed monoclonal antibodies are produced. This amendment is supported by the specification which teaches the five five hybridomas. The claims were also amended to correct dependencies and minor clerical errors. Accordingly, no new matter is added by these amendments to the claims.

**I. Rejection of Claims 51-62, 73-75 and 154 Under 35 U.S.C. § 112, First Paragraph**

Claims 51-62, 73-75 and 154 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner Asserts that the specification does not teach how to make and use any monoclonal antibody that specifically reacts with ant Fas ligand.

It is respectfully submitted that the amendments to the claims render this rejection moot. It is also respectfully submitted that the specification teaches in great detail how to make each of the claimed monoclonal antibodies. Moreover, each of the antibodies has been deposited in a public depository and any and all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a U.S. patent. Accordingly, the rejection of claims 51-62, 73-75 and 154 is respectfully traversed.

**II. Rejection of Claims 51-62, 73-75 and 154 Under 35 U.S.C. § 112, First Paragraph**

Claims 51-62, 73-75 and 154 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to meet the written description requirement. The Examiner asserts that the specification provides only written description of the five specified monoclonal antibodies set forth on page 16 of the specification.

It is respectfully submitted that the amendments to the claims render this ground of rejection moot.

**III. Rejection of Claims 53, 55, 73 and 154 Under 35 U.S.C. § 112, Second Paragraph**

It is respectfully submitted that the amendments to the claims render these grounds of rejection moot.

**IV. Rejection of Claims 51-60, 73-75 and 154 Under 35 U.S.C. § 103(a)**

Claims 51-60, 73-75 and 154 are rejected under 35 U.S.C. § 103(a) as being unpatentably obvious over Takahashi et al., or Suda et al., each in view of Harlow et al. or Campbell et al. The Examiner asserts that the primary references each teach Fas ligands and their effects on apoptosis. The Examiner also relies on the secondary references as teaching how to make and use monoclonal antibodies. Based on this combination of prior art, the Examiner concludes that the present invention would have been obvious to one of ordinary skill in the art at the time of the invention.

Applicants respectfully disagree with the Examiner's conclusion. The present invention is directed to five specified monoclonal antibodies (or active fragments of the monoclonal antibodies), kits containing these monoclonal antibodies and methods for producing these

monoclonal antibodies. Applicants' studies have shown that these monoclonal antibodies are unexpectedly efficient at inhibiting apoptosis at a very low concentration, *i.e.*, 0.01 – 8  $\mu\text{g/ml}$ .

The Examiner relies on the primary references as teaching the effects of Fas ligands in a variety of animals and the generation of generation of Fas ligand-expressing cells. However, the primary references do not disclose or suggest the claimed monoclonal antibodies, nor do these references disclose or suggest the specificity and activity obtained by the antibodies of the invention. The secondary references relied on by the Examiner merely teach how to make and use monoclonal antibodies, but these references do not disclose or suggest the claimed monoclonal antibodies, and do not disclose or suggest the claimed effect of these antibodies on apoptosis. As such, the cited combinations of prior art do not render the claimed invention obvious.

It is respectfully submitted that the rejection of claims 51-60, 73-75 and 154 under 35 U.S.C. § 103(a) over the cited combinations of prior art is traversed.

#### **V. Rejection of Claims 61 and 62 Under 35 U.S.C. § 103(a)**

Claims 61 and 62 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Takahashi et al. or Suda et al. in view of Harlow et al. or Campbell et al. and further in view of the '588 patent. The primary and secondary references are relied on as above, and the '588 patent is relied on as teaching antibody-containing kits. The Examiner asserts that on the basis of the prior art one of ordinary skill in the art would have found it obvious to produce a kit having a monoclonal antibody to detect a Fas ligand in a body sample.

Applicants respectfully disagree with the Examiner's conclusion. The combination of prior art does not teach or suggest the claimed monoclonal antibodies, nor does the cited prior art

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disclose or suggest the effects obtained with the claimed antibodies. Therefore, the cited combination of prior art does not render the present claims directed to kits comprising the claimed monoclonal antibodies obvious.

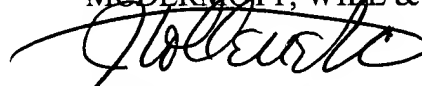
It is respectfully submitted that the rejection of claims 61 and 62 under 35 U.S.C. § 103(a) as unpatentably obvious over the cited prior art is traversed.

It is respectfully submitted that the present application, as amended above, is in condition for allowance, an early notification thereof being earnestly solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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